

OCT - 9 2003

K032724

**Pinnacle³ Radiation Therapy Planning System version 6.6
510(k) Notification**

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Trade Name: Pinnacle³ Radiation Therapy Planning Software

Common Name: Radiation Therapy Planning System

Classification Name: Accelerator, Linear, Medical (per 21CFR section 892.5050)

Predicate Devices: Pinnacle³ Radiation Therapy Planning Software (K993923)
P³ IMRT (K002237)

Device Description: Pinnacle³ Radiation Therapy Planning Software version 6.6 (hereafter Pinnacle³ RTP) provides radiation therapy planning for the treatment of benign or malignant diseases. When using Pinnacle³ RTP, qualified medical personnel may generate, review, verify, approve, print and export the radiation therapy plan prior to patient treatment. Pinnacle³ RTP can provide plans for various radiation therapy modalities including External Beam Treatment, Stereotactic Radiosurgery, and Brachytherapy.

Pinnacle³ RTP is a software package that runs on a Sun UNIX workstation and consists of a core software module (Pinnacle³) and optional software features. These optional software features, commonly referred to as “plug-ins”, are typically distributed separate from the core software product (separate CD-ROM). The device has network capability to other Pinnacle³ workstations and to both input and output devices via local area network (LAN) or wide area network (WAN).

Image data is imported from CT, MR, PET, PET-CT and SPECT devices using a DICOM-compliant interface. A qualified medical professional uses the Pinnacle³ RTP for functions such as viewing and analyzing the patient’s anatomy, and generating a radiation therapy plan. The following are examples of tasks that may be performed by clinicians when using the Pinnacle³ RTP system:

- Evaluate the treatment plan based on radiation-sensitive structures and the tumor.
- Combine both geometric and dosimetric planning on the same platform, including CT simulation data and plans. The CT simulation part of the system is called SmartSim.
- Configure beam variables such as energy, geometry, and beam modifiers such as blocks, wedges, multi-leaf collimators, bolus and compensators.
- Visualize the beam on a display, initiate the dose computation, and set the weight of each beam.

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- Obtain dose measurements from any Points of Interest (POI).
- Perform photon and electron physics modeling, dose algorithm and machine commissioning. This functionality is supported by the Physics Utility Module.
- Evaluate images away from the workstation via a laptop or physician group workstation. The feature that provides remote review is referred to as P³MD.
- Create data for use in conjunction with treatment QA systems.
- Configure, backup, archive, restore, and scripting.
- Evaluate Digitally Reconstructed Radiographs (DRRs) on Pinnacle³ RTP or remote system using DICOM Secondary Capture (SC) Export.

Once complete, Pinnacle³ has the ability to transfer the finished plan to other devices used in the therapy process such as Record and Verify, Linear Accelerator (Linac) Workstations and/or 3rd Party QA systems.

The following Pinnacle³ software features are also available to assist the clinician with the radiation therapy planning process. These features are distributed on standalone CD-ROM media, and installed onto the Pinnacle³ RTP workstation. Corresponding instructions for use such as User Guides or Release Notes are also provided to the clinician for each optional feature.

P³IMRT (Intensity Modulated Radiation Therapy):

P³IMRT combines both forward and inverse planning functionality. The system determines a plan that satisfies the user's treatment goals through an optimization process. The user's treatment goals are specified as objectives and constraints based on dose distribution characteristics.

Syntegra (also referred to as AutoFusion):

Syntegra automates multi-modality image registration and fusion by overlaying images from CT, MR, PET, PET-CT and SPECT devices using a DICOM-compliant interface. This feature provides clinicians with the ability to relate, interpret and contour an image's anatomic and functional information.

In addition to the above, the following software options are available to facilitate image and/or data import and export between radiation therapy devices such as the imaging camera, Pinnacle³ RTP, and Record & Verify system. DICOM is the acronym for Digital Imaging and Communications in Medicine and is an internationally recognized standard for transferring biomedical information such as images and data between devices or over a network.

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DICOM RT:

DICOM RT software is used to support both Structure Set and Radiation Therapy Plan import and export functions. Structure Sets describe regions and points of interest to other systems. Plan information includes beam geometry and delivery information.

DICOM Image:

DICOM Image software is used to support image import and export to and from the Pinnacle³ RTP workstation according to the NEMA DICOM standard, version 3.0. This functionality allows diagnostic imaging devices supporting the DICOM 3.0 standard to interface with the Pinnacle system.

Mitsubishi DME:

A proprietary interface has been created within the Pinnacle³ Treatment Planning software to support plan export to Mitsubishi Record and Verify systems. This interface is called the “Mitsubishi DME” system. This is implemented as a simple file based interface according to a format specified by Mitsubishi.

P³ MD:

P³MD allows for treatment plan review and minor alternations by a physician from a PC-based workstation that is connected to the same network as the primary Pinnacle³ Treatment Planning workstation.

Indications for Use:

Pinnacle³ Radiation Therapy Planning Software is a computer software package intended to provide support for radiation therapy treatment planning for the treatment of benign or malignant disease processes.

Pinnacle³ Radiation Therapy Planning Software assists the clinician in formulating a treatment plan that maximizes the dose to the treatment volume while minimizing the dose to the surrounding normal tissues. The system is capable of operating in both the forward planning and inverse planning modes.

The device is indicated for use in patients deemed to be acceptable candidates for radiation treatment in the judgment of the clinician responsible for patient care.

Plans generated using this software are used in the determination of the course of a patient's radiation treatment. They are to be evaluated, modified and implemented by qualified medical personnel.

Pinnacle³ Radiation Therapy Planning System version 6.6 510(k) Notification

Intended Use:

Pinnacle³ Radiation Therapy Planning Software version 6.6 provides support for conformal arc treatment planning.

Summary of Technological Characteristics Compared to Predicate Devices:

Pinnacle³ Radiation Therapy Planning Software version 6.6 introduces support for conformal arc treatment planning to the existing Pinnacle³ Radiation Therapy Planning System (K993923 and K002237). A conformal arc treatment plan calculates new sets of multi-leaf collimator (MLC) positions at specified intervals through a treatment arc.

Pinnacle³ Radiation Therapy Planning Software version 6.6 incorporates no technological characteristics not currently contained in the predicate devices: Pinnacle³ Radiation Therapy Planning Software (K993923) and P³ IMRT (K002237). Pinnacle³ RTP functionality is contained in one workstation.

Summary of Non-Clinical Tests:

A Hazard Analysis was completed for Pinnacle³ Radiation Therapy Planning Software version 6.6 and hazards were mitigated as appropriate. Verification and Validation test plans were completed in compliance with ADAC Laboratories procedures and will be utilized to demonstrate that the Pinnacle³ Radiation Therapy Planning Software version 6.6 software has met its specifications, demonstrates substantially equivalent performance to the predicate devices and is safe and effective for its intended use.

Summary of Clinical Tests:

Clinical testing is not required to demonstrate substantial equivalence or safety and effectiveness.

Conclusions:

The Pinnacle³ Radiation Therapy Planning Software version 6.6 is substantially equivalent to the predicate devices. It has the same intended use as the predicates and its use does not raise any new or different issues of safety or effectiveness when compared to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2003

ADAC Laboratories, Inc.
% Mr. Jeff Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive, P.O. Box 13995
Research Triangle Park, NC 27709

Re: K032724
Trade/Device Name: Pinnacle³ Radiation Therapy
Planning System, Version 6.6
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charge-particle
radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: September 19, 2003
Received: September 24, 2003

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

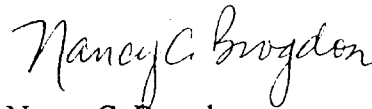
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**Pinnacle³ Radiation Therapy Planning System version 6.6
510(k) Notification**

INDICATIONS FOR USE

510(k) Number (if known):

K032724

Device Name: Pinnacle³ Radiation Therapy Planning System version 6.6

Indications for Use:

Pinnacle³ Radiation Therapy Planning System version 6.6 provides support for conformal arc treatment planning.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

OR

Over-The-Counter-Use ☐

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Proprietary and Confidential
Pinnacle³ RTP version 6.6 - 510(k) Notification
ADAC Laboratories, Inc.
August, 2003

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032724

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